

PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Pu Zhou Confirmation No.: 9310
Serial No.: 10/615,651 Examiner: M. Huson
Filing Date: July 9, 2003 Group Art Unit: 1732
Docket No.: 1001.1662101 Customer No.: 28075
For: METHOD OF FORMING CATHETER DISTAL TIP

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

CERTIFICATE FOR ELECTRONIC TRANSMISSION:

The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 22nd day of December 2006.

By _____


Thu Le-To

Dear Sir:

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this Request.

This Request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached five sheets of arguments.

This Request is signed by an attorney or agent of record.

Respectfully submitted,

Pu Zhou

By his Attorney,


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Date: 12/22/06

Attachment: Five Sheets of Pre-Appeal Brief Request Attachment

P A T E N T

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PRE-APPEAL BRIEF REQUEST FOR REVIEW ATTACHMENT

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Thu Le-To

Dear Sir:

Appellant respectfully requests a Pre-Appeal Brief Review of the pending application, and assert that the Examiner has made clear errors in prosecuting this application. Favorable reconsideration is respectfully requested.

Each of independent claims 1, 35 and 40, stand rejected under 35 U.S.C. §102(e) as being anticipated by Noone et al. (U.S. Patent No. 6,591,472). However, Noone et al. do not disclose all of the claim elements.

The invention of claim 1 is a method of forming a catheter that includes the steps of providing a braid layer and an inner lubricious liner positioned within the braid layer, securing a first polymer segment over the braid layer, cutting through the braid layer and the inner lubricious liner and removing a portion of the braid layer that extends distal from the cut, and "subsequent to the step of cutting through the braid layer and inner lubricious liner, securing a second polymer segment over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position." It is at least this last quoted step of the method that Noone et al. do not teach.

The Examiner asserts to the contrary that Noone et al. do disclose this step, and points to Figure 8, elements 45, 145, column 9, lines 19-20 and column 12, lines 9-11, 35-37 and 52-61 in support of this assertion. However, what Figure 8 shows is a “discrete distal soft tip 45” attached to the catheter body distal the braid layer and distal any other polymer segment. What Figure 8 does not show and the cited sections of the specification fail to teach is securing a second polymer section *over* the braid layer, where the second polymer section extends *over* another polymer section and extends distally of the cutting position.

The essential error in the Examiner’s position is in a misinterpretation of the word “over.” What the Examiner appears to suggest is that because in Figure 8 of Noone et al. distal tip 45 abuts and thereby covers the distal end surfaces of the reinforcement layer 70 and an outer polymer layer 80, it is “over” those layers. This is not the case.

The word “over” has many definitions.¹ The closest definition to that which the Examiner seems to have adopted is “so as to cover.” However, even using this definition cannot result in a reasonable interpretation where the claim is anticipated by Figure 8 of Noone et al. Here is a phrase from claim 1 with the definition substituted for the word: “the second polymer segment extending *so as to cover* the first polymer segment.” If one looks at Figure 8, it is clear that distal tip 45 does not cover in any meaningful sense the first polymer segment. The distal tip 45 may be fairly said to cover the distal surface of the first polymer segment, but that is not what is claimed.

There is an additional difficulty with this definition of “over” in that it is inconsistent with the way the word is used in the claims and in the specification. Just as Applicants cannot say that a word means one thing and then another, so too must an Examiner, in giving claims their broadest reasonable interpretation, consistently interpret claim terminology. For example, claim 1 earlier recites “securing a first polymer segment over the braid layer.” Considering the next phrase in the claim, “the first polymer segment being positioned proximal of the distal end of the braid layer,” no person of skill in the art would reasonably interpret this phrase to cover methods where the first polymer segment distally abuts the braid layer. A second example may be found in the specification, which teaches with reference to Figures 5 and 6, “[a] braid securement segment 50 can be positioned over the reinforcing braid layer 48.”² Just as no one

¹ If one goes to www.answers.com/over, one can see at least thirty definitions.

² Page 11, lines 1-2.

would say that a name tag of ordinary size covers a suit coat, no one of skill in the art would reasonably say that braid securement segment 50 covers reinforcing braid layer 48. In both cases, however, one might reasonably say that the one is over the other, the name tag is over the suit coat and, as Applicant teaches, segment 50 is over layer 48. This suggests that Applicant is using a different definition.

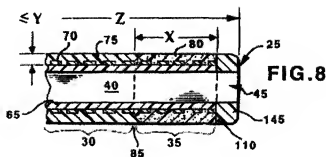
The www.answers.com site lists “in or at a position above or higher than” as one of the definitions of “over.” This definition was apparently written with the Cartesian coordinate system in mind, which specifies locations using three linear axes. But when this definition is applied to the catheter art area, where those of skill in the art typically describe catheter configurations using language more compatible with cylindrical coordinate systems (e.g., proximal, distal, inner, outer, longitudinal, radial, etc.) “in or at a position above” is properly understood as “in or at a position further outward from the longitudinal axis along the same radius.” This is how Applicant uses the term and how Applicant understands those of skill of art to reasonably understand the term in the catheter art area.

This is also the only definition consistent with the specification. If one uses “over” in a Cartesian sense, any layer that is over another is also under another (see Figure 5, for example) and the term has lost any meaning. If one uses “over” to mean further distal on the same longitudinal axis, then one cannot interpret the word “over” consistently throughout the claims. For example, claim 1 recites “securing a first polymer layer over the braid layer.” This cannot mean securing a first polymer layer further distal on the same longitudinal axis as the braid layer as that would render the following phrase in the claim (“the first polymer segment being positioned proximal of the distal end of the braid layer”) nonsensical.

As MPEP 2111 states, “[d]uring patent examination, the pending claims must be ‘given their broadest reasonable interpretation consistent with the specification.’”³ Applicant respectfully submits that the interpretation the Examiner has given the word “over” in claim 1 is not consistent with the specification or with other uses of the word in the claims. When the term “over” is given a proper, consistent meaning, as the Office is required to do, it can be seen that Noone et al. do not anticipate the invention of claim 1.

³ *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000)

Figure 8 of Noone et al. is reproduced below:



As can be seen in Figure 8 of Noone et al., the distal tip 45,145 cannot in any sense be said to be over the braid layer or a first polymer segment; the distal tip at most abuts the distal surfaces of the braid layer and a polymer segment when “over” is given a proper, consistent interpretation. The September 29, 2006 Response After Final provides a fuller explanation of why Noone et al. do not anticipate the claimed invention, when read in light of the above explanation of what “over” can and cannot mean.

Independent claim 35 recites “subsequent to removing the inner layer, the reinforcement layer, and the securement layer distally of the cutting location, securing a polymeric outer segment *over* at least the securement layer such that a portion of the polymeric outer segment extends distally of the cutting location” and independent claim 40 recites “securing a second polymer segment *over* the catheter sub-assembly, the second polymer segment extending *over* the first polymer segment of the catheter sub-assembly and extending distally of the distal end of the catheter sub-assembly; wherein the step of securing the second polymer segment *over* the catheter sub-assembly is performed subsequent to the step of cutting through the braid layer.” (Italics added.) For at least the reasons discussed above with regard to claim 1, the Examiner has made a clear error in claim interpretation and consequently in citing Noone et al. as anticipatory.

Once “over” is given a proper interpretation, the September 29, 2006 Response After Final satisfactorily explains why the other rejections against the pending claims are improper.

As Noone et al. do not teach or suggest all the elements of the claimed invention, the Examiner has failed to establish a proper anticipation rejection. At a minimum, this is a clear error made by the Examiner. Favorable reconsideration is respectfully requested.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Pu Zhou

By his attorney,

A handwritten signature in black ink, appearing to read "David M. Crompton", written over a horizontal line.

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